PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Carl D. Wahlstrand, Robert M. Skime, Ruchika Singhal and Darren A. Janzig	Confirmation No.	4796
Serial No.:	10/730,878		
Filed:	December 09, 2003	Customer No.:	28863
Examiner:	Michael William Kahelin		
Group Art Unit:	3762		
Docket No.:	1023-334US01		
Title:	LEAD CONNECTION MODULE OF A MODULAR IMPLANTABLE MEDICAL DEVICE		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on February 8, 2010.

By: _____
Name: Patricia Cygan

REPLY BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

This is a Reply Brief responsive to the final Office Action mailed April 1, 2009, which finally rejected claims 1–10, 12–15, and 19–21, the Advisory Action mailed July 9, 2009, which affirmed the rejection of the claims, and the Examiner's Answer dated December 9, 2009. The due date for this Reply Brief is February 9, 2010.

No fees are believed to be due at this time. Please charge any fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

TABLE OF CONTENTS

STATUS OF CLAIMS

Claims 1–10, 12–15, and 19–21 are pending and are the subject of this Appeal. The originally filed application included claims 1–14. Claims 15–18 were added in an Amendment filed October 18, 2006; claims 19 and 20 were added in an Amendment filed May 21, 2007; and claim 21 was added in an Amendment filed January 23, 2009. Originally filed claim 11 was canceled in an Amendment filed April 11, 2008 and claims 16–18 were canceled in an Amendment filed January 23, 2009.

Claims 1–5, 8–10, 12, 13, 15, and 19–21 stand rejected under 35 U.S.C. § 102(a/e) as being unpatentable over Berrang et al. (U.S. Patent No. 6,358,281 B1; hereinafter "Berrang"), or in the alternative, as being unpatentable under 35 U.S.C. § 103(a) over Berrang in view of Correas (U.S. Patent No. 6,112,120). Claims 6, 7, and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang in view of Correas.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following grounds of rejection to be reviewed on appeal:

(1) The first ground of rejection to be reviewed on appeal is the rejection of claims 1–5, 8–10, 12, 13, 15, and 19–21 under 35 U.S.C. § 102(a/e) as being unpatentable over Berrang, or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Berrang in view of Correas.

(2) The second ground of rejection to be reviewed on appeal is the rejection of claims 6, 7, and 14 under 35 U.S.C. § 103(a) as being unpatentable over Berrang in view of Correas.

ARGUMENT

In the Examiner's Answer to Appellant's Appeal Brief filed on September 14, 2009, the Examiner provided a clarification of the rejection of the claims. For brevity, this Reply Brief only addresses aspects of these new arguments. Accordingly, this Reply Brief is not intended to address all arguments provided in the Examiner's Answer, and Appellant requests full consideration of all arguments set forth in the Appeal Brief filed on September 14, 2009. In addition, Appellant respectfully requests separate review of each set of claims argued under separate headings in the Appeal Brief.

Claims 1–5, 8–10, 12, 13, 15, 20, and 21

Independent claim 1 recites an implantable medical device comprising at least two interconnected modules, each of the modules comprising a respective one of at least two housings to house the respective modules and an overmold that at least partially encapsulates each of the housings and is at least partially flexible to allow relative motion between the modules. According to claim 1, the overmold comprising a lead connection module configured to accept an external lead, where the external lead is separable from the lead connection module and where the lead connection module comprises a feed-through wire that electrically couples to the external lead.

In support of the rejection of claim 1 under 35 U.S.C. § 102(a/e), the Examiner characterized the bridge 6 of the Berrang device as the lead connection module of claim 1 and the junction 16 of the Berrang device as the external lead of claim 1 that is separable from the lead connection module. The Examiner further asserted that the junction 16 is necessarily separable from the bridge 6 by, e.g., wire cutters because the materials from which they are constructed are necessarily capable of being cut by such a tool.[1] As discussed in the Appeal Brief filed on September 14, 2009, the Examiner's proposed use of wire cutters to cut the junction 16 of Berrang does not demonstrate that the junction 16 is inherently separable from the bridge 6. Specifically, the use of wire cutters would result in maintenance of the proximal portion of the junction (on the proximal side of the cut) within the bridge 6 and severance of only the distal portion of the junction 16 (on the distal side of the cut) from the bridge 6. Thus, the

[1] Examiner's Answer dated December 9, 2009 at page 6.

junction 16 would be cut into two pieces upon the application of the wire cutters, whereby one of the pieces would remain within the bridge 6.[2]

In the Response to Arguments provided in the Examiner's Answer, the Examiner stated:

> The claim does not require the entire lead to be separable nor does the claim preclude the consideration of only the portion of the conductor distal to element 6 to be part of the 'external lead.' In other words, the claim language allows any portion of the conductor within element 6 to not be considered part of the claimed 'external lead.' In fact, the examiner has indicated that this portion of the conductor within element 6 is the claimed 'feed through,' . . . [3]

It appears that the Examiner clarified his interpretation of Berrang. Specifically, it appears that the Examiner characterized the proximal portion of the junction 16 remaining within the bridge 6 (after cutting the junction 16 with wire cutters) of Berrang as the feed-through wire of claim 1 and the distal portion of the junction 16 (after cutting the junction 16 with wire cutters) of Berrang as the external lead of claim 1. As previously discussed, upon cutting the junction 16 with wire cutters, the proximal portion of the junction 16 would remain within the bridge 6. If the proximal portion of the junction 16 were to remain within the bridge 6, the bridge 6 (characterized by the Examiner as the lead connection module of claim 1) would be unable to accept the distal portion of the junction 16 because the proximal portion of the junction 16 would occupy the entire space within the bridge 6. The Examiner's interpretation of Berrang results in a system in which the bridge 6, characterized by the Examiner as the lead connection module of claim 1, is unable to accept the distal portion of the junction 16, characterized by the Examiner as the external lead of claim 1. Consequently, Berrang fails to disclose or suggest an implantable medical device comprising a lead connection module configured to accept an external lead, as required by claim 1.

In the Appeal Brief filed on September 14, 2009, Appellant also argued that the Examiner's proposed use of wire cutters to cut the junction 16 would render the device of Berrang dysfunctional by severing the connection between the electrode array 10 and the microphone 9 and the remainder of the Berrang device.[4] As a result, the Examiner's proposed modification would render the Berrang device unsatisfactory for its intended purpose, and, accordingly, there is no suggestion or modification to make the proposed modification.[5]

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[2] Appeal Brief filed on September 14, 2009 at page 7.
[3] Examiner's Answer dated December 9, 2009 at page 9.
[4] Appeal Brief filed on September 14, 2009 at pages 7–8.
[5] *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

In the Response to Arguments provided in the Examiner's Answer, the Examiner stated:

> Appellant further argued that cutting this external lead from the lead connection module would render the device inoperable because it cannot be replaced ... However, the claim language does not require replace-ability.[6]

As previously discussed, the Examiner asserted that the junction 16 of Berrang is necessarily separable from the bridge 6 by, e.g., wire cutters, because the materials from which the junction 16 is constructed are necessarily capable of being cut by such a tool. Accordingly, it appears that the Examiner adopted an unreasonably broad interpretation of the phrase "wherein the external lead is separable from the lead connection module" of claim 1, where the interpretation includes an external lead that is permanently severed from the lead connection module by, e.g., wire cutters. This interpretation is both unreasonable and unreasonably broad, particularly in view of Appellant's disclosure.

Appellant respectfully submits that the Examiner's interpretation of the phrase "wherein the external lead is separable from the lead connection module" is unreasonably broad when Appellant's specification is properly considered. As stated by the Federal Circuit in *Phillips v. AWH Corp.*, "[t]he Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'"[7] Citing this decision, the MPEP instructs that "[d]uring patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification."[8] The Examiner's interpretation of claim 1 is inconsistent with Appellant's specification as it would be interpreted by one of ordinary skill in the art.

For example, according to Appellant's specification, the lead connection modules 613 provide a mechanism for electrically connecting electronics within control module 610 to one or more external leads 643.[9] As illustrated in FIG. 6A (reproduced below), external leads 643 may be inserted into a lead connection module 613 and be separable from IMD 601. In this manner, lead connection modules 613 may be configured to accept external leads 643.[10] FIG. 8B (also

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[6] Examiner's Answer dated December 9, 2009 at page 10.
[7] 415 F.3d 1303, 1316 (Fed. Cir. 2005), *citing In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 USPQ2d 1827 (Fed. Cir. 2004).
[8] *See* MPEP § 2111.
[9] Appellant's originally-filed disclosure at paragraph [0051].
[10] Amendment to the Specification filed on October 31, 2008.

reproduced below) illustrates that external lead 843 is inserted into the lead connection module in order to connect the external lead 843 to electronics within control module 810 of the IMD.[11]

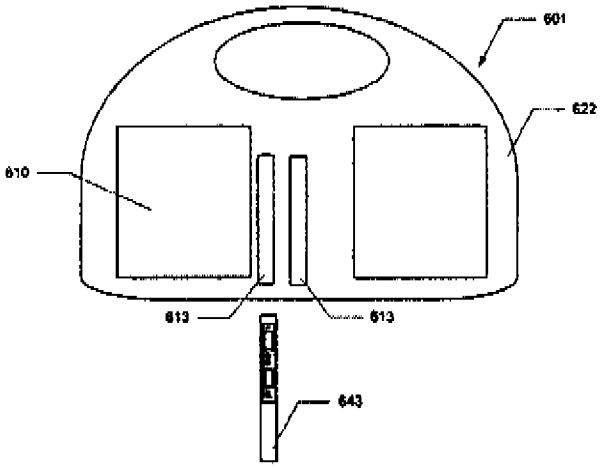

FIG. 6A

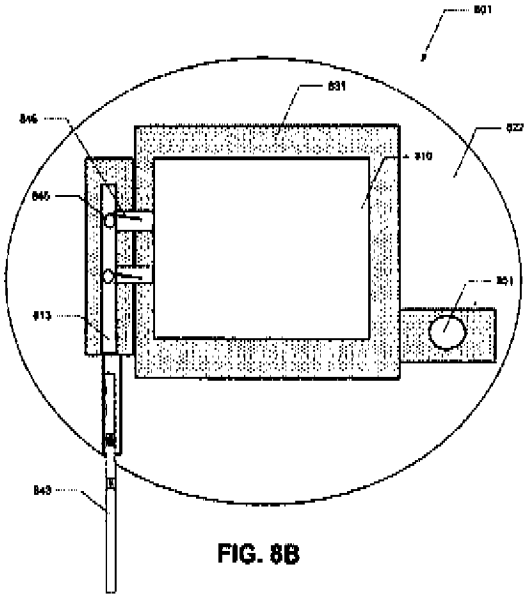

FIG. 8B

Appellant respectfully disagrees that one of ordinary skill in the art would, in light of Appellant's specification, interpret the external lead of claim 1 that is separable from the lead connection module as being permanently separable by e.g., wire cutters, as asserted by the Examiner. Such an interpretation would render the device dysfunctional, as previously discussed in the Appeal Brief filed on September 14, 2009. Even if "the claim language does not require replace-ability," Appellant submits that a person of ordinary skill in the art would not interpret Appellant's claims in a manner that would render the device of Appellant's claims dysfunctional in light of Appellant's specification. The Examiner's rejection of Appellant's claims should be reversed based on at least the Examiner's unreasonably broad interpretation of Appellant's claim.

In support of the alternative rejection of claim 1 under 35 U.S.C. § 103(a), the Examiner asserted that Correas discloses a lead that is manually separable and re-attachable to a lead connection module. The Examiner further asserted that it would have been obvious to modify the device disclosed by Berrang with the lead of Correas to provide the predictable result of allowing convenient immobilization of a lead on a generator by a surgeon without risk of

[11] Appellant's originally-filed disclosure at paragraph [0058].

inopportune disconnection.[12] In the Response to Arguments provided in the Examiner's Answer, the Examiner further stated "[t]his feature of allowing immobilization by a surgeon (as opposed to a unitary structure) provides such advantages (as would be recognized by an artisan in the field) as: allowing the lead to be manipulated to the desired location and then immobilized on the generator to avoid the problems of the bulky device getting in the way during the implantation procedure and allowing for later replacement of the device if needed while maintaining the lead in the body so as not to disrupt the tissue in-growth around the lead."[13]

As an initial matter, Berrang fails to disclose or suggest that any component of the device of Berrang is "bulky" and "get[s] in the way during the implantation procedure." To the contrary, Berrang discloses that the "totally implantable cochlear prosthesis of the present invention is designed to address the limitations of the prior art and to . . . improve the aesthetics and practical problems of coping with the relatively bulky external components of conventional cochlear prostheses."[14] Thus, Berrang addresses the problems associated with bulky components, presumably by providing a device that is not relatively bulky. For at least this reason, one of ordinary skill in the art would not have looked to Correas to modify Berrang in order to "avoid the problems of a bulky device getting in the way during the implantation procedure," as asserted by the Examiner.

Moreover, Berrang discloses that the device of Berrang is "designed to reduce the surgical complexity and time needed by a surgeon for device implantation."[15] In view of this disclosure, one of ordinary skill in the art would not have modified the device of Berrang to include the manually separable probe and the probe connector of Correas. Specifically, the modification proposed by the Examiner would appear to increase the surgical complexity by requiring two devices, i.e., the probe and probe connector of Correas, instead of one, i.e., the cochlear prosthesis of Berrang. Additionally, the modification would appear to increase the time needed by a surgeon for device implantation because the modification would require the additional step of connecting the probe and the probe connector upon implantation of the device, in comparison to implantation of the one-piece Berrang device. For at least these reasons, the modification proposed by the Examiner contradicts one of the fundamental objectives of the

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[12] Examiner's Answer dated December 9, 2009 at pages 6–7.
[13] Examiner's Answer dated December 9, 2009 at page 10.
[14] Berrang at col. 2, ll. 28–32.
[15] Berrang at col. 2, ll. 36–38.

Berrang device. Consequently, one of ordinary skill in the art at the time of the invention would not have looked to Correas to modify Berrang in the manner proposed by the Examiner.

In support of the rejection of claim 1, the Examiner asserted that the bridge 6 of Berrang necessarily includes a feed-through wire that electrically couples to the junction 16 because the junction 16 stimulates using the circuitry and power source.[16] As previously discussed in the Appeal Brief filed September 14, 2009, Berrang discloses that the underside of each ceramic substrate 24, 25, which the Examiner characterized as being a "housing" for different modules[17], contain "a plurality of electrically insulated electrical lead-throughs."[18] Accordingly, the Berrang device does not necessarily include a separate lead connection module that includes a feed-through wire, and the cables 7, 8 that extend through the junction 16 may directly couple to the battery 18 and electronics 21, which the Examiner characterized as "modules," via the electrical lead-throughs in the ceramic substrates 24, 25. In the Response to Arguments provided in the Examiner's Answer, the Examiner stated "[i]n regards to the alleged lack of a 'separate feed-through wire,' nothing in the claim language requires the feed-through wire to be 'separate.' The claimed 'feed-through wire' is merely the portion of the conductor that necessarily connects the external electrodes to the internal circuitry within element 6."[19]

Although claim 1 does not explicitly require a "separate feed-through wire," claim 1 requires a lead connection module that comprises a feed-through wire and an external lead that is separable from the lead connection module. In other words, the feed-through wire of claim 1 is included in the lead connection module, which is separable from the external lead. Thus, the portion of the junction 16 that connects the external electrodes to the internal circuitry within the bridge 6 of Berrang cannot reasonably be characterized as the feed-through wire of claim 1. More specifically, the junction 16 of Berrang cannot reasonably be characterized as both the feed-through wire that is included in the lead connection module and the external lead that is separable from the lead connection module of claim 1.

In support of the rejection of claim 1, the Examiner characterized the battery 18 and electronics 21 shown in FIGS. 2 and 3 of Berrang as two modules each having a housing encapsulated by an overmold. The Examiner further asserted that the ceramic substrates 24, 25

[16] Examiner's Answer dated December 9, 2009 at page 6.
[17] Examiner's Answer dated December 9, 2009 at page 6.
[18] Berrang at col.11, ll. 48–50.
[19] Examiner's Answer dated December 9, 2009 at page 11.

and the snap domes 20, 23 define a housing for the battery 18 and electronics 21, or, alternatively, the support disc 33 houses the electronics 21 and the battery inherently comprises its own housing.[20] As described in the Appeal Brief filed September 14, 2009, Appellant respectfully disagrees that the Examiner's characterization is reasonable.[21] In the Examiner's Answer, the Examiner responded to Appellant's remarks by stating "the fact that the elements [characterized by the Examiner as the housings of claim 1] serve other purposes (e.g., providing a mounting surface for a piezoceramics actuator") does not obviate the fact that they do at least partially surround (or 'house') the modules. The Examiner's broadest reasonable interpretation of 'housing' does not require total encapsulation, but only an element that at least partially contains or covers."[22]

Regardless of whether the ceramic substrates 24, 25, the snap domes 20, 23, and the support disc 33 of Berrang "serve other purposes," the Examiner mischaracterized these components of Berrang. Specifically, the Examiner appears to have characterized any component of Berrang in contact with the battery 18 and the electronics 21 as a housing of claim 1. Appellant respectfully disagrees that the ceramic substrates 24, 25, the snap domes 20, 23, and the support disc 33 surrounds the modules in any manner. The Examiner's interpretation of the term "housing" effectively vitiates the requirement that the housing of claim 1 houses the modules. Indeed, the Examiner's interpretation of "housing" merely requires the housing to be in contact with the components, which is unreasonable, particularly in light of Appellant's specification.

In the Examiner's Answer, the Examiner further stated "regardless of whether any single one of Berrang's elements 'house' the modules, Figure 2 clearly shows that a combination of elements completely surrounds each of the modules 18 and 21, and thus provides a 'housing.'" [23] Even if Berrang discloses a combination of elements completely surrounding each of the modules 18 and 21, an assertion with which Appellant does not necessarily agree, claim 1 does not merely require a combination of elements completely surrounding each of the modules of claim 1. Instead, claim 1 requires at least two interconnected modules, each of the modules

[20] Examiner's Answer dated December 9, 2009 at page 6.
[21] Appeal Brief filed on September 14, 2009 at pages. 11–12.
[22] Examiner's Answer dated December 9, 2009 at page 11.
[23] Examiner's Answer dated December 9, 2009 at page 11.

comprising a respective one of at least two housings to house the respective modules. Berrang fails to disclose or suggest this feature of claim 1.

Claim 19

In support of the rejection of claim 19, the Examiner asserted that it would have been an obvious matter of deign choice to modify Berrang such that the electronics 21 were housed in a hermetic housing "because applicant has not disclosed that the individual hermetic seals provides an advantage, is used for a particular purpose, or solves a stated problem."[24] As discussed in the Appeal Brief filed September 14, 2009, the "obvious matter of design choice" rationale was used in *In re Kuhle*,[25] which relates to a rearrangement of parts, but the Examiner appeared not to use the "obvious matter of design choice" rationale to support an assertion that it would have been obvious to rearrange parts of the Berrang system to arrive at Appellant's claimed invention.[26] In the Examiner's Answer, the Examiner responded by asserting that "[rearrangement of parts] is precisely the case in this instance. The Examiner asserted that rearranging the hermetic seal to house each of the modules individually instead of the housing as a whole would have been an obvious matter of design choice because both configurations predictably prevent substances from entering or escaping the system, and would be a mere arrangement of the housing to house the modules individually instead of the entire system."[27]

The Examiner has erroneously relied on *In re Kuhle* to support the rejection of claim 19. According to the MPEP, "if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court."[28] Appellant respectfully disagrees that the facts presented in *In re Kuhle* are sufficiently similar to those of the present case to support a rejection using the "rearrangement of parts" rationale. According to *In re Kuhle*, the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice.[29] In contrast, the Examiner suggested that separating the housing of Appellant's claims into several housings to form individual housings for each of the individual modules, including the control module, would be an obvious

[24] Examiner's Answer dated December 9, 2009 at page 8.
[25] *In re Kuhle*, 526 F.2d 533 (CCPA 1975).
[26] Appeal Brief filed on September 14, 2009 at page 14.
[27] Examiner's Answer dated December 9, 2009 at page12.
[28] *See* MPEP § 2144.04.
[29] *See* MPEP § 2144.04(VI) citing *In re Kuhle*.

matter of design choice. Although moving the housing may reasonably be considered a rearrangement of parts, Appellant respectfully disagrees that dividing the housing into several pieces, each of which defines a hermetic housing, can reasonably be considered a rearrangement of parts, particularly in view of the facts of *In re Kuhle*.

In the Examiner's Answer, the Examiner also stated "[f]urther, duplicating hermetic seals by, e.g., coating the individual modules as well as the device as a whole would provide the predictable result of added security of the seal."[30] Appellant's claim 19 does not require duplicating hermetic seals. Instead, Appellant's claim 19 requires that the housing of the control module is hermetic. Moreover, Berrang fails to provide any indication that electronics 21 that are enclosed in a hermetic housing would have been useful or would even be feasible with the snap dome 20 functionality required by Berrang.[31]

For at least the reasons provided above and the reasons provided in the Appeal Brief filed September 14, 2009, the Examiner has failed to establish a *prima facie* case of anticipation or obviousness for Appellant's claims 1–10, 12–15, and 19–21. Reversal of the rejections is respectfully requested.

CONCLUSION

For at least these reasons and the reasons discussed in Appellant's Appeal Brief, the Examiner has failed to establish a *prima facie* case for non-patentability of Appellant's claims 1–10, 12–15, and 19–21. In view of Appellant's arguments present in this Reply Brief and in the previously-filed Appeal Brief, the rejection of Appellant's claims was improper and should be reversed. Reversal of all pending rejections and allowance of all pending claims is respectfully requested.

Date: February 8, 2010

By: 

Name: Jessica H. Kwak
Reg. No.: 58,975

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.286.8346
Facsimile: 651.735.1102

[30] Examiner's Answer dated December 9, 2009 at page 12.
[31] *See* Berrang at col. 12, ll. 32–46.